IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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INVENTOR ..... Theresa Ditter
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EXAMINER ..... Eric D. Blatt
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TITLE ..... "Vascular Sealing Device With Locking Hub"

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DECLARATION OF ZACHARY J. TEGELS
UNDER 37 CFR 1.132

I, Zachary J. Tegels, declare the following:

1. I have worked as a design engineer in the medical device industry for 8.5 years, and have been designing vascular closure devices for St. Jude Medical for the past 3 years.

2. I am knowledgeable about filaments used for treatment of the body, especially when used with vascular closure devices to seal a vessel puncture.

3. Those of ordinary skillin the art of vascular closure devices understand that the term "suture" is interchangeable with the term "filament" to identify the structure used to connect together an anchor and a sealing portion of a vascular closure device.

4. The filaments used in vascular closure devices are generally flexible structures having a small cross section that would prohibit formation of features within the filaments such as notches or steps used as ratchet features. Any attempt to add such features to the filament, even if such a modification were possible, would weaken the

filament and render it useless for its intended purpose of holding together the anchor and sealing pad. Thus, there is no motivation whatsoever to form ratchet features directly into filaments used for vascular closure devices.

5. I have reviewed U.S. Patent No. 5,545,178 to Kensey et al., U.S. Published Application No. 2002/0183787 to Wahr et al., and U.S. Published Application No. 2003/0176890 to Buckman et al. Persons of ordinary skill in the art of vascular closure devices (*e.g.*, the device disclosed by Kensey) would have no motivation to look to the devices of Wahr and Buckman in considering how to improve a vascular closure device.

6. The Wahr apparatus is directed to sealing a patent foramen ovale in the heart, which is a very different anatomical structure from a vascular puncture. The Wahr device has no need for a separate filament since the tether 16 is directly connected to the anchor 12. The tether 16 comprises a multifilar braided polymeric material that is not bioresorbable. In contrast, filaments typically used with vascular closure devices comprise bioresorbable materials. Further, Wahr provides no suggestion or motivation of a pivotal connection of the anchor 12 to a ratchet mechanism with a filament since the tether 16 is directly connected to the anchor. The closure device 10 disclosed by Wahr does not comprise a sealing plug. Further, Wahr fails to disclose a ratchet mechanism that terminates proximal of a distal end of a filament. Wahr only discloses a ratchet mechanism generally with no disclosure or suggestion whatsoever of combining the ratchet mechanism with a vascular closure device or the type of filament used with vascular closure devices.

7. The Buckman apparatus is used for achieving hemostasis in solid visceral wounds such as abdominal viscera. This type of treatment using this type of device is very different as compared to the environment where vascular closure devices are used. Buckman discloses a ratchet device that includes a bolt 10 having a plurality of serrations 20 along at least one of its ends 18, and a pressure plate 26 with ratcheting lock 28 that ratchets along the serrations 20. The structure, materials, size, and other aspects of the Buckman device render it so far removed from vascular closure devices that those of skill in the art of vascular closure devices, such as myself, would have no motivation to reference Buckman, much less incorporate features of Buckman into, a vascular closure device. Even if one of skill in the art were to reference the Buckman device, there is no suggestion whatsoever by Buckman of using a ratchet mechanism in combination with a filament, sealing plug, or two-piece locking apparatus.

8. Kensey discloses a holding member 40 constructed as a disc that slides along the filament 42 to compress the sealing member 36 toward the anchoring member 38 (*see* FIGS. 6 and 7). The holding member 40 is held from moving proximally after compressing the sealing member 36 by positioning knots on a proximal side of the holding member 40. Even with knots in place, the holding member 40 can slide distally along the filament toward the anchor so that it is not fixed relative to the filament. The holding member 40 is a single-piece device. The holding member 40 is positioned proximal of the sealing member 36 and does not at any time pass through any portion of the sealing member 36. Based on my review of Kensey, Wahr and Buckman, there is clearly no teaching, motivation or suggestion to replace the holding member 40 of Kensey with one of the ratchet mechanisms of Wahr and Buckman. There is no

suggestion by Kensey that such a modification would be desirable or productive. Further, such a modification, even if it were possible, would significantly alter the structure and operation of the Kensey device. Thus, the claims of the present application would not be obvious in view of Kensey, Wahr and Buckman.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code. 21 02 DEC 2011

Dated this 2nd day of ~~November~~ DECEMBER, 2011.

02 DEC 2011

Zachary J. Vegels